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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,844	08/03/2001	Gary K. Michelson	101.0084-01000	8295

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT PAPER NUMBER

3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/921,844

Applicant(s)

MICHELSON, GARY K.

Examiner

Bruce E. Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Petition Decision dated 1/20/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 131, 219 and their dependent claims is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and its dependent claims is/are allowed.
- 6) ☒ Claim(s) 131 and 219 and their dependent claims is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/22/05; 10/21/05; 1/25/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Final Office action dated 1/7/04 has been withdrawn. The Petition decision, dated 1/20/05, indicated that the rejection under 35 U.S.C. 112, second paragraph, made the Final action premature. It is the Examiner's position that applicant's amendment dated 10/9/03 including new drawings, specifically, new figures 1A-1C, necessitated this rejection. The Examiner understands the limitation "motion preserving device", but does not understand how figure 1C meets this limitation, and, thus questioned its meaning. Never the less, the rejection under 35 U.S.C. 112, second paragraph, has been withdrawn.

The Petition decision further indicated that withdrawing claims 131, 133, 135, 137-145, 205, 206, 213-215, and 272-276 from prosecution being drawn to a nonelected species was improper. It is the Examiner unyielding position that amended claim 131, which is supported only by the new drawing 12B, does not read on the elected embodiment shown in figure 12 as stated by the Examiner in the Advisory Action dated 4/23/04. Applicant's arguments dated 10/9/03, page 23, states, "Applicant added new Fig. 12B, which shows an example of a left facet facing a left side of the implant and a right facet facing the right side of the implant." This was not the orientation originally presented. Never the less, claims 131, 133, 135, 137-145, 205, 206, 213-215, and 272-276 have been added back into prosecution and a new Final Office action follows.

Response to Arguments

Applicant's arguments filed 10/9/03 have been fully considered but they are not persuasive. Regarding the rejection of claim 219 in view Aebi et al, Aebi et al teaches the steeper angled face can be "from about 0 to 30 degrees" which the Examiner interprets to include negative angles.

Allowable Subject Matter

Claims 1 and its depending claims are allowed.

Specification

The amendment filed 10/9/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The following proposed drawings and associated descriptions added to the specification is considered new matter.

Figures 1A and 1B are new matter. These figures show a completely new spinal implant embodiment in which one having ordinary skill in the art reading the original claims (of 09/457,228) would not have conceived. It is noted that the embodiment was incorporated from U.S. Patent No. 5,593,409, however that drawing does not show the current projections. The combination of the current invention surface projections and

previous embodiment is new matter. Note that proposed Figure 1A shows the surface projects at an angle relative the leading and trailing ends which is new matter.

Figure 1C is new matter. One skilled in the art would not interpret a motion preserving device to be a rectangle.

Figure 12B changes the orientation of the projection and facet names.

Figure 14A and 14B – it is mechanically impossible to have anything but a V-shape. Please confirm that claim 18 is original to 09/457,228.

Applicant is required to cancel the new matter in the reply to this Office Action.

Note that proposed drawing 14C is approved by the Examiner.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, all claims must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Due to the large number of claims only some specific claims will be addressed as examples purposes only. ***It is Applicant's responsibility to ensure all claimed limitations are shown in the drawings or to remove limitations or cancel the claims of the limitations not shown.***

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Examples of claims not shown: Claim 21 – arcuate upper and lower surfaces; claim 22-24, Claim 47 – “cap”; 228-232, 269.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 131 and its depending claim (at least claims 131, 133, 135, 137-145, 205, 206, 213-215, and 272-276) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 131 now claims, as supported by applicant's specification, “rearward facet 326” as the left facet and the “forward facet 324” as the right facet. This is new matter. This changes the orientation of the projections and facet names.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 131 and its depending claim (at least claims 131, 133, 135, 137-145, 205, 206, 213-215, and 272-276) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 131, "*at least a first and second portion arranged to form an included angle greater than 90 degrees between said first and second portion arranged to form an included angle greater than 90 degrees between said first and second portion of the perimeter*" is ambiguous. The term "portion" is undefined by applicant's specification and is unclear if applicant is referring to the sides of the perimeter of the facets or simply any as desired portion.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 131 and 219 and their depending claims (at least 219, 228-255, 277-284 and (131, 133, 135, 137-145, 205, 206, 213-215, and 272-276 as far as the scope can be determined)) are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebi et al (6,482,233).

Aebi et al teaches a spinal implant comprising bone engaging structures that are generally pyramid-shaped formed on the upper and lower surfaces of the implant. The engaging structures are slanted towards the anterior therefore having a forward (anterior) facing facet that is shorter than a rearward facing facet and said forward facing facet has a steeper slope; the structures further include side facets. Applicant claims the opposite Aebi et al claiming the bone engaging structures slant rearward (posteriorly). However, both Aebi et al and applicant teach the bone engaging structures slant in a direction such to allow ease of insertion and to avoid retropulsion. See Aebi et al column 4, lines 30-34 and applicant's specification page 5, lines 5-9 and lines 15-19. It would have been obvious to one having ordinary skill in the art to have slanted the bone engaging structures of Aebi et al posteriorly such that the implant could be introduced posterior-laterally and/or resist movement in the direction towards the spinal cord when a surgeon deems it necessary. Note that Aebi et al teaches the steeper angled face can be "from about 0 to 30 degrees" which the Examiner interprets to include negative angles.

Many of applicant's dependent claims claim a wide range of possibilities, for example, an angle can be less than 90 degrees, perpendicular, or greater than 90 degrees; the groove can be v-shaped, u-shaped, box-like shape; etc, lacking any criticality in the specification, the use of any claimed variation, range, or configuration in lieu of those used in the references solves no stated problem and produces no benefits and would have been an obvious matter of design choice for someone skilled in the art.

Additionally, many of the dependent claims claim elements/materials/shapes/tools/etc. which are taught by the reference or are well known in the prosthetic art and would have been obvious to one having ordinary skill.

Claims 131 and 219 and their depending claims (at least 219, 228-255, 277-284 and 131, 133, 135, 137-145, 205, 206, 213-215, and 272-276 as far as the scope can be determined) are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al (6,258,125) in view of Fraser (6,432,106).

Paul et al teaches a spinal implant comprising a plurality of pyramid-shaped projections 12, as shown in figures 9, 10A, and 11, formed on the upper and lower surfaces of the implant; see 3:42. The projections are slanted towards the trailing end, therefore, having a forward facing facet which is longer than a rearward facet. The projections further include side facets and a rectangular base.

However, Paul et al is silent regarding the rearward facet having a negative direction of inclination or a portion of the projection extending outside of the perimeter of the base.

Fraser teaches a similar spinal implant having surface projections 50 wherein the rearward facet 72 can either have a positive slope (like that of Paul et al) or negative slope as shown in figure 10. It would have been obvious to one having ordinary skill in the art to have formed the rearward facet of Paul et al forming a negative slope such that the forward facet and the rearward facet both have a negative inclination (claim 1) which

produces a portion that extend outside the perimeter of a base portion (claim 57) such that the projections dig into the bone and better resists expulsion.

Many of applicant's dependent claims claim a wide range of limitations, for example, elements/materials/shapes/tools/etc which lack criticality in the specification, the use of any limitations in lieu of those used in the references solves no stated problem and produces no benefits and would have been an obvious matter of design choice for someone skilled in the art. Additionally, these limitations are well known in the prosthetic art and would have been obvious to one having ordinary skill.

Additionally, it would have been obvious to one having ordinary skill to have used any bone growth material known in the art or to have constructed the implant from any material known in the art for their known properties and characteristics.

Claims 131 and 219 and their depending claims (at least 219, 228-255, 277-284 and (131, 133, 135, 137-145, 205, 206, 213-215, and 272-276 as far as the scope can be determined)) are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al (6,258,125) in view of Lin (6,325,827).

Paul et al teaches a spinal implant comprising a plurality of pyramid-shaped projections 12, as shown in figures 9, 10A, and 11, formed on the upper and lower surfaces of the implant; see 3:42. The engaging structures are slanted towards the trailing end, therefore, having a forward facing facet which is longer than a rearward facet. However, Paul et al is silent regarding the rearward facet having a negative direction of inclination.

Lin also teaches a spinal implant having projections or "angled barbs" 24 comprising forward facets 24a and rearward facets 24b; see figure 18. Lin teaches, the *"front face 24a of the barbs 24 is angled rearward relative to the direction of insertion of the implant 20 (like Paul et al). The rear face 24b of the barbs 24 is angled approximately vertical. The rear face may also be angled rearwardly relative the direction of the insertion of the implant 20" (see 5:6 et seq.).*

It would have been obvious to one having ordinary skill in the art to have formed the rearward facet of Paul al "angled rearwardly" as taught by Lin, forming a negative slope such that the forward facet and the rearward facet both have a negative inclination (claim 1) which produces a portion that extend outside the perimeter of a base portion (claim 57) such that the projections better resists repulsion and implant migration.

Many of applicant's dependent claims claim a wide range of limitations, for example, elements/materials/shapes/tools/etc which lack criticality in the specification, the use of any limitations in lieu of those used in the references solves no stated problem and produces no benefits and would have been an obvious matter of design choice for someone skilled in the art. Additionally, these limitations are well known in the prosthetic art and would have been obvious to one having ordinary skill.

Additionally, it would have been obvious to one having ordinary skill to have used any bone growth material known in the art or to have constructed the implant from any material known in the art for their known properties and characteristics.

Regarding new claims 113 and 116, it would have been obvious to one having ordinary skill in the art to have utilized a plurality of through holes on the implant to allow for ingrowth and anchoring of the implant.

Regarding BMP, see 5:47 of Lin.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read 'BSN', with a long horizontal line extending to the right.

BRUCE SNOW
PRIMARY EXAMINER